BioTime provides California researchers access to clinical grade embryonic stem cell lines

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CIRM has negotiated on behalf of its grantees and California-based researchers immediate access to five research grade versions of clinical-grade human embryonic stem cell lines described in Crook et al, 2007 The Generation of Six Clinical-Grade Human Embryonic Stem Cell Lines Cell Stem Cell Nov;1(5):490-4) (ESI-014, ESI-017, ESI-035, ESI-051 and ESI-053). In addition, BioTime has agreed to provide future access to the GMP versions of these lines in one year. The letter agreement between CIRM and BioTime sets forth pre-negotiated terms and a template Material Transfer Agreement in order to assist in accelerating access. Key terms of the agreement provide:

- Immediate access to CIRM grantees and California researchers of research grade cell lines, at no cost through April 30, 2011, and thereafter $2,500per ampoule; no other charges for research use.
- Access to GMP grade lines along with a letter of cross-reference to a Biologics Master File (BMF) containing the manufacturing and controls information and additional documentation needed to establish GMP compliance and complete DNA sequence information on the lines will be available at the supplier's cost within 12 months of November 22, 2010.
- For Commercial Use: a royalty cap of 2% of net sales reducible to 1.5% in the event additional royalties are owed in resulting product commercialization. The parties may seek to negotiate more favorable terms. Cost per ampoule to be negotiated, in good faith, and to approximate costs of BioTime and its subsidiary.
- CIRM has not obtained agreements with or commitments from other third parties. Permissions, licenses, from third parties, for instance by WARF, may be required.

Interested parties should contact Walter Funk at BioTime:
(510) 521-3390
wfunk@biotimemail.com

- Read the letter of agreement [pdf]
- Read the MTA [pdf]